

**THE EURASIAN ECONOMIC COMMISSION**

**THE BOARD**

**RECOMMENDATION**

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| June 8, 2021 | **No. 10** | Moscow |

**On amending the List of Standards Applying which on Voluntary Basis Will Result in Compliance of Medical Devices, in Whole or in Part, with the General Requirements for Medical Device Safety and Efficiency, Requirements for their Marking and Operational Documentation.**

The Eurasian Economic Commission's Board, based on paragraph 2 of Article 3, paragraph 4 of Article 4 and paragraph 4 of Article 7 of the Agreement on Unified Principles and Rules for the Circulation of Medical Devices (Medical Accessories and Medical Equipment) within the Eurasian Economic Union dated December 23, 2014, and in accordance with paragraph 110 of General Requirements for Medical Device Safety and Efficiency, Requirements for their Marking and Operational Documentation approved by Decision No. 27 of the Eurasian Economic Commission's Council dated February 12, 2016

recommends to the Member States of the Eurasian Economic Union to apply the List of Standards Applying which on Voluntary Basis Will Result in Compliance of Medical Devices, in Whole or in Part, with the General Requirements for Medical Device Safety and Efficiency, Requirements for their Marking and Operational Documentation at the lapse of 6 months from the date of publication of this Recommendation on the website of the Eurasian Economic Union considering the amendments according to the Annex (Annex to Recommendation No. 17 of the Eurasian Economic Commission's Board dated September 4, 2017).

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| Chairman of the Board  of the Eurasian Economic Commission | M. Myasnikovich |

ANNEX

to Recommendation of the Board

of the Eurasian Economic Commission

No. 10 dated June 8, 2021

**AMENDMENTS**

**to be made to the List of Standards Applying which on Voluntary Basis**

**Will Result in Compliance of Medical Devices, in Whole or in Part,**

**with the General Requirements for Medical Device Safety and Efficiency,**

**Requirements for their Marking and Operational Documentation**

1. Section I:

a) items 5, 28, 35, 45, 57, 80, 97, 129 and 130 shall be read as follows:

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| --- | --- | --- | --- | --- | --- | --- | --- |
| 5 | GOST R 58236-2020 | Medical elastic manufactured articles for the compression. General technical requirements. Test methods | August 1, 2021 |  | 5, 6 | 3 |  |
| 5, 6 | 4 |  |
| 5, 6 | 5 |  |
| 5, 6 | 6 |  |
| 5, 6 | 7 |  |
| 5, 6 | 8 |  |
| 5, 6 | 12 |  |
| 28 | GOST ISO 10993-3-2018  (ISO 10993-3:2014, IDT) | Medical devices. Biological evaluation of medical devices.  Part 3. Tests for genotoxicity, carcinogenicity and reproductive toxicity | August 1, 2021 |  | 4 – 7 | 12 |  |
| 4 – 7 | 13 |  |
| 4 – 7 | 15 |  |
| 35 | GOST ISO 11135-2017  (ISO 11135:2014, IDT) | Sterilization of health-care products Ethylene oxide. Requirements for the development, validation and routine control of a sterilization process for medical devices | August 1, 2021 |  | 4 – 12 | 18 |  |
| 4 – 12 | 19 |  |
| 45 | GOST ISO 13485-2017  (ISO 13485:2016, IDT) | Medical devices. Quality management systems. Requirements for regulatory purposes | August 1, 2021 |  | 4.1, 4.2, 5.1, 5.3 – 5.6, 6.4, 7.1 – 7.6, 8.2.2, 8.2.3, 8.2.4, 8.3, 8.4, 8.5.1 – 8.5.3 | 3 |  |
| 4.1, 4.2, 5.1, 5.3 – 5.6, 6.4, 7.1 – 7.6, 8.2.2, 8.2.3, 8.2.4, 8.3, 8.4, 8.5.1 – 8.5.3 | 4 |  |
| 4.1, 4.2, 5.1, 5.3 – 5.6, 6.4, 7.1 – 7.6, 8.2.2, 8.2.3, 8.2.4, 8.3, 8.4, 8.5.1 – 8.5.3 | 5 |  |
| 4.1, 4.2, 5.1, 5.3 – 5.6, 6.4, 7.1 – 7.6, 8.2.2, 8.2.3, 8.2.4, 8.3, 8.4, 8.5.1 – 8.5.3 | 6 |  |
| 4.1, 4.2, 5.1, 5.3 – 5.6, 6.4, 7.1 – 7.6, 8.2.2, 8.2.3, 8.2.4, 8.3, 8.4, 8.5.1 – 8.5.3 | 7 |  |
| 4.1, 4.2, 5.1, 5.3 – 5.6, 6.4, 7.1 – 7.6, 8.2.2, 8.2.3, 8.2.4, 8.3, 8.4, 8.5.1 – 8.5.3 | 8 |  |
| 57 | GOST R ISO 14644-1-2017 (ISO 14644-1:2015, IDT) | Cleanrooms and associated controlled environments.  Part 1. Classification of air cleanliness by particle concentration | August 1, 2021 |  | 4, 5, Annex A | 20 |  |
| 80 | GOST R ISO 14630-2017  (ISO 14630:2012, IDT) | Non-active surgical implants. General requirements | August 1, 2021 |  | 4 – 8 | 3 |  |
| 4 – 8 | 4 |  |
| 4, 5, 7, 8, 10 | 5 |  |
| 4 – 10 | 6 |  |
| 4 – 8 | 7 |  |
| 5, 7 | 8 |  |
| 4 – 8 | 12 |  |
| 4, 6 – 8, 10 | 13 |  |
| 6, 7, 8 | 14 |  |
| 9, 10 | 16 |  |
| 9, 10 | 18 |  |
| 9, 10 | 19 |  |
| 9, 10 | 20 |  |
| 9, 10 | 21 |  |
| 6 | 22 |  |
| 6 | 23 |  |
| 5, 6, 11 | 27 |  |
| 4, 5, 6 | 28 |  |
| 9 | 58 |  |
| 9, 10 | 60 |  |
| 97 | GOST R ISO 22675-2019  (ISO 22675:2016, IDT) | Prosthetics. Testing of ankle-foot devices and foot units. Requirements and test methods | August 1, 2021 |  | 5 ­10, 15, 16, 17 | 4 |  |
| 5 – 10, 15, 16, 17 | 7 |  |
| 5, 20 | 9 |  |
| 5, 20 | 27 |  |
| 5 – 10, 15, 16, 17 | 46 |  |
| 20 | 58 |  |
| 129 | GOST R IEC 60601-2-47-2017 (IEC 60601-2-47:2012, IDT) | Medical electrical equipment. Part 2-47. Particular requirements for basic safety and essential performance of ambulatory electrocardiographic systems | August 1, 2021 |  | 201.4 – 201.17 | 3 |  |
| 201.4 – 201.17 | 4 |  |
| 201.4 – 201.17 | 5 |  |
| 201.4 – 201.17 | 6 |  |
| 201.4 – 201.17 | 7 |  |
| 201.4 – 201.17 | 8 |  |
| 201.11 | 12 |  |
| 201.11 | 14 |  |
| 201.11 | 15 |  |
| 201.15 | 26 |  |
| 201.16 | 27 |  |
| 201.9, 201.11 – 201.13, 201.15, 201.17, 202 | 28 |  |
| 201.11 | 29 |  |
| 201.7 | 30 |  |
| 201.12 | 31 |  |
| 201.10 | 34 |  |
| 201.14 | 38 |  |
| 201.13 | 39 |  |
| 201.12 | 42 |  |
| 201.17, 202 | 43 |  |
| 201.17, 202 | 44 |  |
| 201.8 | 45 |  |
| 201.9 | 46 |  |
| 201.9 | 47 |  |
| 201.9 | 48 |  |
| 201.8, 201.15 | 49 |  |
| 201.15 | 50 |  |
| 201.11 | 51 |  |
| 201.12, 201.15 | 52 |  |
| 201.12, 201.15 | 53 |  |
| 201.12 | 54 |  |
| 201.7, 201.12, 201.16 | 55 |  |
| 201.7, 201.12, 201.16 | 56 |  |
| 201.7, 201.12, 201.16 | 57 |  |
| 201.7 | 58 |  |
| 201.7 | 65 |  |
| 130 | GOST R IEC 60601-2-49-2018 (IEC 60601-2-49:2011, IDT) | Medical electrical equipment. Part 2-49. Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment | August 1, 2021 |  | 201.4 – 201.17 | 3 |  |
| 201.4 – 201.17 | 4 |  |
| 201.4 – 201.17 | 5 |  |
| 201.4 – 201.17 | 6 |  |
| 201.4 –201.17 | 7 |  |
| 201.4 – 201.17 | 8 |  |
| 201.11 | 12 |  |
| 201.11 | 14 |  |
| 201.11 | 15 |  |
| 201.15 | 26 |  |
| 201.16 | 27 |  |
| 201.9, 201.11 – 201.13, 201.15, 201.17, 202 | 28 |  |
| 201.11 | 29 |  |
| 201.7 | 30 |  |
| 201.12 | 31 |  |
| 201.10 | 34 |  |
| 201.14 | 38 |  |
| 201.13 | 39 |  |
| 201.12, 208 | 42 |  |
| 201.17, 202 | 43 |  |
| 201.17, 202 | 44 |  |
| 201.8 | 45 |  |
| 201.9 | 46 |  |
| 201.9 | 47 |  |
| 201.9 | 48 |  |
| 201.8, 201.15 | 49 |  |
| 201.15 | 50 |  |
| 201.11 | 51 |  |
| 201.12, 201.15 | 52 |  |
| 201.12, 201.15 | 53 |  |
| 201.12 | 54 |  |
| 201.7, 201.12, 201.16 | 55 |  |
| 201.7, 201.12, 201.16 | 56 |  |
| 201.7, 201.12, 201.16 | 57 |  |
| 201.7 | 58 |  |
| 201.7 | 65 | ; |

b) add items 156 – 163 with the following contents:

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| 156 | GOST 31621-2012 | Implants for surgery. Total joint replacement. Determination of durability of friction unit's work of hip endoprostheses by a method of torque estimation | August 1, 2021 |  | 3.1 – 5.9,  Annex А | 6, 7,  12 3),  28 8),  46 |  |

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| 157 | GOST R IEC 60601-2-8-2017 (IEC 60601-2-8:2010, IDT) | Medical electrical equipment. Part 2-8. Particular requirements for the basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV | August 1, 2021 |  | 201.4 – 201.17 | 3 |  |
| 201.4 – 201.17 | 4 |  |
| 201.4 – 201.17 | 5 |  |
| 201.4 – 201.17 | 6 |  |
| 201.4 – 201.17 | 7 |  |
| 201.4 – 201.17 | 8 |  |
| 201.11 | 12 |  |
| 201.11 | 14 |  |
| 201.11 | 15 |  |
| 201.15 | 26 |  |
| 201.16 | 27 |  |
| 201.9, 201.11 – 201.13, 201.15, 201.17 | 28 |  |
| 201.11 | 29 |  |
| 201.7 | 30 |  |
| 201.12 | 31 |  |
| 201.10 | 34 |  |
| 201.10 | 35 |  |
| 201.10 | 36 |  |
| 201.10 | 37 |  |
| 201.14 | 38 |  |
| 201.13 | 39 |  |
| 201.12 | 42 |  |
| 201.17 | 43 |  |
| 201.17 | 44 |  |
| 201.8 | 45 |  |
| 201.9 | 46 |  |
| 201.9 | 47 |  |
| 201.9 | 48 |  |
| 201.8, 201.15 | 49 |  |
| 201.15 | 50 |  |
| 201.11 | 51 |  |
| 201.12, 201.15 | 52 |  |
| 201.12, 201.15 | 53 |  |
| 201.12 | 54 |  |
| 201.7, 201.12, 201.16 | 55 |  |
| 201.7, 201.12, 201.16 | 56 |  |
| 201.7, 201.12, 201.16 | 57 |  |
| 201.7 | 58 |  |
| 201.7 | 65 |  |

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| 158 | GOST R IEC 60601-2-10-2019 (IEC 60601-2-10:2016, IDT) | Medical electrical equipment. Part 2-10. Particular requirements for the basic safety and essential performance of nerve and muscle stimulators | August 1, 2021 |  | 201.4 – 201.17 | 3 |  |
| 201.4 – 201.17 | 4 |  |
| 201.4 – 201.17 | 5 |  |
| 201.4 – 201.17 | 6 |  |
| 201.4 – 201.17 | 7 |  |
| 201.4 – 201.17 | 8 |  |
| 201.11 | 12 |  |
| 201.11 | 14 |  |
| 201.11 | 15 |  |
| 201.15 | 26 |  |
| 201.16 | 27 |  |
| 201.9, 201.11 – 201.13, 201.15, 201.17, 202 | 28 |  |
| 201.11 | 29 |  |
| 201.7 | 30 |  |
| 201.12 | 31 |  |
| 201.10 | 34 |  |
| 201.14 | 38 |  |
| 201.13 | 39 |  |
| 201.12 | 42 |  |
| 201.17, 202 | 43 |  |
| 201.17, 202 | 44 |  |
| 201.8 | 45 |  |
| 201.9 | 46 |  |
| 201.9 | 47 |  |
| 201.9 | 48 |  |
| 201.8, 201.15 | 49 |  |
| 201.15 | 50 |  |
| 201.11 | 51 |  |
| 201.12, 201.15 | 52 |  |
| 201.12, 201.15 | 53 |  |
| 201.12 | 54 |  |
| 201.7, 201.12, 201.16 | 55 |  |
| 201.7, 201.12, 201.16 | 56 |  |
| 201.7, 201.12, 201.16 | 57 |  |
| 201.7 | 58 |  |
| 201.7 | 65 |  |
| 159 | GOST R IEC 60601-2-24-2017 (IEC 60601-2-24:2012, IDT) | Medical electrical equipment. Part 2-24. Particular requirements for the basic safety and essential performance of infusion pumps and controllers | August 1, 2021 |  | 201.4 – 201.17 | 3 |  |
| 201.4 – 201.17 | 4 |  |
| 201.4 – 201.17 | 5 |  |
| 201.4 – 201.17 | 6 |  |
| 201.4 – 201.17 | 7 |  |
| 201.4 – 201.17 | 8 |  |
| 201.11 | 12 |  |
| 201.11 | 14 |  |
| 201.11 | 15 |  |
| 201.15 | 26 |  |
| 201.16 | 27 |  |
| 201.9, 201.11 – 201.13, 201.15, 201.17, 202, 206 | 28 |  |
| 201.11 | 29 |  |
| 201.7 | 30 |  |
| 201.12 | 31 |  |
| 201.10 | 34 |  |
| 201.14 | 38 |  |
| 201.13 | 39 |  |
| 201.12, 208 | 42 |  |
| 201.17, 202 | 43 |  |
| 201.17, 202 | 44 |  |
| 201.8 | 45 |  |
| 201.9 | 46 |  |
| 201.9 | 47 |  |
| 201.9 | 48 |  |
| 201.8, 201.15 | 49 |  |
| 201.15 | 50 |  |
| 201.11 | 51 |  |
| 201.12, 201.15 | 52 |  |
| 201.12, 201.15 | 53 |  |
| 201.12 | 54 |  |
| 201.7, 201.12, 201.16 | 55 |  |
| 201.7, 201.12, 201.16 | 56 |  |
| 201.7, 201.12, 201.16 | 57 |  |
| 201.7 | 58 |  |
| 201.7 | 65 |  |
| 160 | GOST ISO 10993-10-2011  (ISO 10993-10:2002, IDT) | Medical devices. Biological evaluation of medical devices. Part 10. Tests for irritation and delayed-type hypersensitivity | August 1, 2021 |  | 4 – 8 | 12 |  |
| 4 – 8 | 13 |  |
| 4 – 8 | 15 |  |
| 161 | GOST R ISO 14708-1-2012 (ISO 14708-1:2000, IDT) | Implants for surgery. Active implantable medical devices. Part 1. General requirements for safety, marking and information to be provided by the manufacturer | August 1, 2021 |  | 5 – 28 | 3 |  |
| 5 – 28 | 4 |  |
| 7 – 12 | 5 |  |
| 5 – 28 | 6 |  |
| 5 – 28 | 7 |  |
| 5 – 28 | 8 |  |
| 5 – 27 | 12 |  |
| 7, 10 – 12, 14 – 19 | 13 |  |
| 5-7, 10 – 12, 14 | 14 |  |
| 5-7, 10 – 12, 14 | 16 |  |
| 6, 7, 10 – 12, 14 | 18 |  |
| 7, 10, 12 | 21 |  |
| 14 | 22 |  |
| 5, 6, 13 | 27 |  |
| 20 – 27 | 28 |  |
| 8, 9, 11, 13 | 58 |  |
| 8, 9, 11, 13 | 60 |  |
| 162 | GOST R ISO 5832-5-2010 (ISO 5832-5:2005, IDT) | Implants for surgery. Metallic materials. Part 5. Wrought cobalt-chromium-tungsten-nickel alloy | August 1, 2021 |  | 3 – 6 | 12 |  |
| 163 | MVI.MN 6232-2020 (MP Qualification Certificate No. 1208/2020  dated January 29, 2020) | Mass concentration of acetaldehyde and ethylene  oxide in aqueous extracts from medical devices sterilized with ethylene oxide. Measurement Procedure by Gas Chromatography | August 1, 2021 |  | 2 – 12 | 3, 15 | ; |

c) delete items 3, 4, 20, 24, 32 and 63.

2. Items 5, 9, 14, 19 and 31 of Section II shall be read as follows:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 5 | GOST ISO 11135-2017  (ISO 11135:2014, IDT) | Sterilization of health-care products Ethylene oxide. Requirements for the development, validation and routine control of a sterilization process for medical devices | August 1, 2021 |  | 4 – 11 | 74 |  |
| 9 | GOST ISO 13485-2017  (ISO 13485:2016, IDT) | Medical devices. Quality management systems. Requirements for regulatory purposes | August 1, 2021 |  | 4.1, 4.2, 5.1, 5.3 – 5.6, 6.4, 7.1 – 7.6, 8.2.2, 8.2.3, 8.2.4, 8.3, 8.4, 8.5.1 – 8.5.3 | 3 |  |
| 4.1, 4.2, 5.1, 5.3 – 5.6, 6.4, 7.1 – 7.6, 8.2.2, 8.2.3, 8.2.4, 8.3, 8.4, 8.5.1 – 8.5.3 | 4 |  |
| 4.1, 4.2, 5.1, 5.3 – 5.6, 6.4, 7.1 – 7.6, 8.2.2, 8.2.3, 8.2.4, 8.3, 8.4, 8.5.1 – 8.5.3 | 5 |  |
| 4.1, 4.2, 5.1, 5.3 – 5.6, 6.4, 7.1 – 7.6, 8.2.2, 8.2.3, 8.2.4, 8.3, 8.4, 8.5.1 – 8.5.3 | 6 |  |
| 4.1, 4.2, 5.1, 5.3 – 5.6, 6.4, 7.1 – 7.6, 8.2.2, 8.2.3, 8.2.4, 8.3, 8.4, 8.5.1 – 8.5.3 | 7 |  |
| 4.1, 4.2, 5.1, 5.3 – 5.6, 6.4, 7.1 – 7.6, 8.2.2, 8.2.3, 8.2.4, 8.3, 8.4, 8.5.1 – 8.5.3 | 8 |  |
| 4.1, 4.2, 5.1, 5.3 – 5.6, 6.4, 7.1 – 7.6, 8.2.2, 8.2.3, 8.2.4, 8.3, 8.4, 8.5.1 – 8.5.3 | 69 |  |
| 4.1, 4.2, 5.1, 5.3 – 5.6, 6.4, 7.1 – 7.6, 8.2.2, 8.2.3, 8.2.4, 8.3, 8.4, 8.5.1 – 8.5.3 | 70 |  |
| 4.1, 4.2, 5.1, 5.3 – 5.6, 6.4, 7.1 – 7.6, 8.2.2, 8.2.3, 8.2.4, 8.3, 8.4, 8.5.1 – 8.5.3 | 71 |  |
| 14 | GOST R ISO 14644-1-2017 (ISO 14644-1:2015, IDT) | Cleanrooms and associated  controlled environments. Part 1. Classification of air cleanliness by particle concentration | August 1, 2021 |  | 4, 5, Annex A | 75 |  |

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| 19 | GOST R EN 13612-2010  (EN 13612:2002, IDT) | Performance evaluation of  in vitro diagnostic medical devices | August 1, 2021 |  | 4.2, 4.3, 4.4, 4.5 | 6 |  |
| 4.5 | 7 |  |
| 4.5 | 72 |  |
| 4.2, 4.3, 4.4, 4.5 | 85 |  |
| 4.5 | 90 |  |
| 4.3 | IV.10 |  |
| 31 | GOST R ISO 15197-2015  (ISO 15197:2013, IDT) | In vitro diagnostic test systems.  Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus | August 1, 2021 |  | 4.3, 4.4, 6.5, 7 | 5 |  |
| 4.2, 6 | 6 |  |
| 4.3, 4.4 | 7 |  |
| 7 | 9 |  |
| 5.1 | 11 |  |
| 6.4 | 69 |  |
| 4.3, 5.2 – 5.6, 5.8,  5.10 – 5.12 | 82 |  |
| 5.7 | 83 |  |
| 6 | 85 |  |
| 6 | 90 |  |
| 5.2 | 94 |  |
| 5.3, 5.6 | 95 |  |
| 5.2 | 99 |  |
| 4.4, 7, 8 | 102 |  |
| 4.4, 7, 8 | 103 |  |
| 4.4, 7, 8 | 104 | . |

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